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To: Tina Lee **From:** Clark A. Puntigam
Fax: 571-273-0299 **Date:** December 23, 2005
Phone: **Pages:** 14 including cover page
Re: Apparatus for Treatment

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PATENT

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Clark A. Puntigam
Name

Clark A. Puntigam
Signature

Dec. 23, 2005

Date of Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Stephen M. Meginnis III et al
Serial No : 09/316,990
Filed : May 24, 1999
Title : APPARATUS AND METHOD FOR TREATMENT OF XEROSTOMIA

Art Unit: 3764

Examiner: F.C. Mathew

MAIL STOP APPEAL BRIEF-PATENTS
COMMISSIONER OF PATENTS
P.O. BOX 1450
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SUPPLEMENTAL APPEAL BRIEF

Dear Sir:

This is appellants' supplemental brief for the appeal of the above-identified patent application, which now includes sections IX (Evidence appendix) and X (Related Proceedings appendix).

I. Real party in interest

The real party in interest of the above application is Philips Oral Health Care, Inc., purchaser of the original assignee of the application, Optiva Corporation.

II. Related appeals and interferences

There are no related appeals or interferences to this pending appeal.

III. Status of claims

Claims 1-5 and 9-19 are pending in this application. Claims 10, 11 and 15-19 have been withdrawn. Claims 1-5, 9 and 12-14 have been rejected and are now being appealed.

IV. Status of amendments

No amendments have been filed subsequent to the final rejection.

V. Summary Of claimed subject matter

The subject matter defined in the sole independent claim (Claim 1) under appeal in this application is an apparatus for the treatment of xerostomia. Xerostomia is a salivary hypofunction condition of the mouth, generally known as "dry mouth". Xerostomia is characterized by a significant decrease in or in some cases a complete lack of salivary secretion and flow thereof into the oral cavity. Clinically, the condition of xerostomia is described as a dramatic reduction in the secretion of unstimulated saliva.

The claimed apparatus includes a driver assembly capable of producing a vibrating action at a drive frequency. This is shown in Figure 3 and is described in the specification from page 3, line 28 (driver 10) to page 4, line 9. Reference is made to U.S. Patent Nos. 5,189,751 and 5,378,153 relative to a suitable driver assembly.

The claimed apparatus further includes a stimulator assembly which is operatively connected to the driver assembly. The stimulator assembly includes a stimulator member comprising a plurality of cylindrical elastomeric finger elements for vibrating the salivary member of the user to produce a significant increase in saliva production into the oral cavity. The elastomeric finger elements have a particular configuration and arrangement, including rounded top portions, a length within the range of 0.2-0.5 inches and a cross-sectional diameter within the range of 0.06-0.25 inches. The elastomeric material has a durometer in the range of 20-60 shore A. The finger elements with the specified characteristics, driven at a particular frequency and amplitude, produce the desired vibrational effect on the salivary member, which in turn produces an increase in saliva production into the mouth. The above structure is shown in Figure 3 (stimulator elements 44) and is described on page 5, lines 3-27, page 6, lines 18-34 and page 8, line 20 - page 9, line 4.

VI. Grounds of rejection to be reviewed on appeal

Claims 1-5, 9 and 12-14 have been rejected under 35 U.S.C 103(a) as unpatentable over Giuliani (5,189,751) in view of Michaels (5,040,260), and further in view of Roberts (5,987,688).

VII. Argument

The invention is an article for accomplishing a particular function, namely, increasing saliva production by stimulating the salivary glands. The article includes a stimulator assembly having particular physical characteristics, and is driven at a particular

frequency and amplitude to accomplish the function.

Applicants agree that Giuliani discloses a driver assembly which is capable of producing the drive action for the stimulator assembly. As noted above, the examiner in the final action stated that Giuliani lacks the stimulator assembly claimed by the applicants. The examiner cites Michaels and Roberts relative to the stimulator assembly. The claimed stimulator assembly includes a plurality of elastomeric finger elements having specific physical characteristics which, when vibrated at a particular frequency and amplitude by the drive member, produce a stimulating effect on the salivary glands, resulting in increased saliva production. The specific physical characteristics set forth in claim 1 include the length of the elastomeric finger elements, the cross-sectional diameter thereof and the durometer (hardness) value of the particular elastomeric material comprising the finger elements.

Claim 1, in addition to the specific physical characteristics indicated above, specifies that the finger elements are sufficiently flexible, resilient and soft that a sufficient vibrational effect is produced on the salivary member to produce a significant increase in saliva.

Michaels teaches a toothbrush head for cleaning and polishing teeth and massaging and stimulating the gums. The Michaels toothbrush head includes elastomer projections 10 which are truncated cylinders configured to penetrate in interproximal areas, while elastomer projections 12 are conical and penetrate beneath the gums and into the crevices between the teeth. Michaels does not disclose any dimensions for the projections.

Applicants agree that one skilled in the art could substitute the elastomeric projections of Michaels for the bristles of Giuliani, but only for the purpose of teeth cleaning and polishing or gum stimulation. Combining Michaels with Giuliani is problematic in the context of xerostomia. There is no motivation from the Michaels reference or any other reference to substitute the Michaels toothbrush head for Giuliani's to address the problem of xerostomia. It is only applicants' disclosure which provides such a teaching. There is no teaching which links the teaching of Michaels and its particular toothbrush head structure with the problem of xerostomia.

Further, as the examiner points out, Michaels lacks any teaching relative to applicants' claimed characteristics of the individual stimulator elements (fingers) which produce the desired salivary gland stimulating effect.

Without any evidence that would motivate one skilled in the art to use the toothbrush head of Michaels with the Giuliani driver to solve the problem of xerostomia and without any teaching which would lead one skilled in the art to use elastomeric finger elements having the particular claimed physical characteristics, applicants' claims are patentable over Giuliani and Michaels.

It is recognized that Roberts was cited by the examiner as teaching elastomeric bristle members having the claimed physical characteristics not specifically taught by Michaels. That could be a logical position if the claimed invention were a toothbrush/gum massager. The use of Roberts, however, has the same basic problem as

Michaels. As explained above, applicants' invention is an article for treatment of xerostomia which produces an increase in saliva into the oral cavity. As discussed above, there is no teaching or motivation which lead one skilled in the art to use the Michaels brushhead structure with the Giuliani driver to solve the problem of xerostomia, and likewise there is no teaching, apart from applicants' own disclosure, of modifying Michaels with Roberts to come up with elastomeric finger elements having the claimed physical characteristics to produce an increase in saliva from the salivary glands.

One skilled in the art, faced with the well-recognized and long-standing problem of xerostomia, in the absence of applicants' disclosure, is without any teaching which would motivate him/her to use the Michaels toothbrush head with the Giuliani drive, and further is without any teaching of modifying Michaels with the Roberts teaching. It is the applicants, and the applicants alone, who have provided the critical teaching of using elastomeric members having the particular claimed physical characteristics in a stimulator assembly which, when vibrated at a particular amplitude and frequency, solves the problem of xerostomia.

Without the linking teaching provided by the applicants, one skilled in the art would simply pass over the Michaels teaching, even as made more particular by Roberts, as simply being directed to teeth cleaning/gum massage. There is nothing in Michaels or Roberts which link teeth cleaning and/or gum massage to vibration of the salivary glands to increase production of saliva into the mouth and thus solve the problem of xerostomia.

It is thus not obvious to combine Michaels and Roberts with Giuliani to produce an article for treatment of xerostomia. Claim 1 and claims 2-5, 9 and 12-14, which are dependent thereon, are thus patentable over Giuliani, Michaels and Roberts.

Conclusion

It is thus respectfully requested that the rejection of the rejected claims be overturned.

The Commissioner is authorized to charge Deposit Account No. 14-1270 for the appeal brief filing fee of \$500 and any deficiency or to credit any overpayment thereto.

Respectfully submitted,

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Enclosures: VIII. Claims Appendix
IX. Evidence Appendix
X. Related Proceedings Appendix

VIII. Claims appendix

1. An article for use in treatment of xerostomia, comprising:

a driver assembly capable of producing a vibrating action at a drive frequency;

a stimulator assembly operatively connected to said driver assembly such that the stimulator assembly vibrates in response to operation of the driver assembly, the stimulator assembly including a stimulator member for vibrating a salivary member, wherein the vibration of the stimulator member has such a frequency and amplitude and wherein the stimulator member is so configured and arranged, comprising substantially only a plurality of cylindrical elastomeric finger elements, substantially all of which have rounded top portions with a selected length within the range of 0.2-0.5 inches and a cross-sectional diameter within the range of 0.06-0.25 inches and are made from an elastomeric material having a durometer in the range of 20-60 shore A, which is sufficiently flexible, resilient and soft, that when the stimulator member is brought into contact with the salivary member, a sufficient vibrational effect is produced on the salivary member that a significant increase in the saliva production into the oral cavity results.

2. An apparatus of claim 1, wherein the stimulator assembly has a resonant frequency which is approximately the same as the drive frequency of the driver assembly.

3. An apparatus of claim 2, wherein the resonant frequency increases slightly when the apparatus is placed under load.

4. An apparatus of claim 2, wherein the drive frequency is within the range of 40 Hz to 500 Hz.

5. An apparatus of claim 1, wherein the driver assembly drives the stimulator member at a frequency which results in a random movement of tips of the stimulator member.

6. (canceled)

7. (canceled)

8. (canceled)

9. An apparatus of claim 1, wherein the finger elements are of equal length.

10. (withdrawn) An apparatus of claim 7, wherein the fingers are of unequal length.

11. (withdrawn) An apparatus of claim 1, wherein the stimulator member comprises a base portion and a single rib which extends upwardly therefrom, the single rib being having a height within the range of 0.2-0.5 inches, a length within the range of 0.2-1 inch, and a thickness within the range of 0.06-0.5 inches.

12. An apparatus of claim 1, wherein the stimulator

assembly and the stimulator member have such a configuration as to be suitable only for tissue vibration outside of the oral cavity.

13. An apparatus of claim 1, wherein the salivary member is a salivary gland and vibration thereof results in a substantial increase in the production of saliva by the salivary gland.

14. An apparatus of claim 1, wherein the salivary member is a salivary duct and vibration thereof results in a substantial increase in flow of saliva through said salivary duct.

15. (withdrawn) A method for treatment of xerostomia, comprising the steps of:

vibrating a stimulator assembly such that the tip of a stimulator member portion thereof moves at a selected drive frequency and amplitude; and

moving the vibrating stimulator into contact with a salivary member or tissue adjacent thereto, wherein the frequency and amplitude are such and the stimulator member is configured and arranged so as to physically vibrate the salivary member so as to produce a significant increase in saliva into the human mouth.

16. (withdrawn) A method of claim 15, wherein the resonant frequency of the stimulator assembly is approximately the same as the drive frequency.

17. (withdrawn) A method of claim 15, wherein the drive frequency is within a range of 40 Hz-500 Hz.

18. (withdrawn) A method of claim 15, wherein the salivary member is a salivary gland and vibration thereof results in a substantial increase in the production of saliva.

19. (withdrawn) A method of claim 15, wherein the salivary member is a salivary duct and vibration thereof results in a substantial increase in flow of saliva through said salivary duct.

IX. Evidence appendix

None

X. Related proceedings appendix

None